



**GLOVES:**

[https://drive.google.com/file/d/1j5k3pipz0DTcsu0Yh\\_yi8Miwv9rcB8N4/view?usp=sharing](https://drive.google.com/file/d/1j5k3pipz0DTcsu0Yh_yi8Miwv9rcB8N4/view?usp=sharing)

**PRODUCT DOCUMENTS BELOW**



## NITRILE EXAMINATION GLOVES

NON-STERILE. POWDER FREE. LATEX FREE

### ADVANCED NITRILE

RFB *Advanced Nitrile* gloves are premium quality Nitrile Examination gloves made with Chemical resistant Nitrile with long cuff for increased protection.

Designed to provide the comfort of Latex with the protection of Nitrile which is Chemical, Abrasion and Tear Resistant.

They contain no Natural Latex proteins and our unique low modulus formulation offers superior comfort and fit as well as excellent tactile sensitivity.

Suitable for applications such as Hospitals, Laboratories, Cleaning, Light Duty Maintenance and Food Processing

#### Products Attributes

- Chemical resistant Nitrile for greater protection
- 240 mm length Standard Cuff
- Ambidextrous for use in either hand
- Polymer coated for ease of damp hand donning
- Beaded cuff design to prevent roll down
- CE Certified as per PPE CAT III
- EU Food Contact safe

#### Specifications

- Nitrile
- Textured
- Powder Free
- Polymer coated
- Blue Colour

### Ordering Information

**Product Code: RFB/006**

Reference No.	Size
RN240 1165	S
RN240 1170	M
RN240 1175	L
RN240 1180	XL



#### Packaging Configuration

Non-Sterile – 100 Pcs/ Box, 10 Boxes/ Carton



0321



## Technical Data Sheet

*Nitrile Examination Gloves– 240 mm, Non-Sterile, Powder Free*

Trade Name	RFB Nitrile Examination Gloves, 240 mm		
Product Conformance	EN 455; PPE Directive 89/686/ EEC (EN 420, EN 374, EN 388) ASTM D6319-19; EC 1935/2004 for Food contact		
Material	Nitrile (Acrylonitrile Butadiene Rubber)		
Cuff Design	Beaded		
Colour	Blue		
Type	Ambidextrous		
Powder Content	Powder Free		
Product Specification			
Dimension	Size	Palm Width (mm)	Length (mm)
	Small	85±5mm	240
	Medium	95±5mm	240
	Large	105±5mm	240
	X Large	115±5mm	240
Thickness (Single Wall)	Palm	4.0 Mil / 0.10 mm	
	Characteristics	Before ageing	After ageing
Physical Properties	Tensile Strength (MPa)	14 min	14 min
	Ultimate Elongation (%)	500 min	400 min
Quality Inspection  AQL 1.5	Inspection Criteria		Sampling Plan / AQL
	Dimension		S2- AQL 4.0
	Physical Properties		S2- AQL 4.0
	1000 ml Water Leak Test		G1-AQL 1.5
	Visual Inspection- Major		G1-AQL 2.5
	Visual Inspection - Minor		G1-AQL 4.0
Packaging Configuration			
Non-Sterile Packing	100 Pieces per Inner box; 10 Inner boxes per Master Carton (1000 Pieces)		



**RFB LATEX LIMITED**

78-80, Noida Special Economic Zone, Noida - 201305, India

Website: [www.rfblatex.com](http://www.rfblatex.com) Email: [rfblatex@rfblatex.com](mailto:rfblatex@rfblatex.com)



# RFB LATEX LIMITED

24,78,79,80, Noida Special Economic Zone, Noida – 201305, UP, India

Tel: +91 120 4944 150; Fax: +91 11 6617 3971

E-mail: [rfblatex@rfblatex.com](mailto:rfblatex@rfblatex.com) Website: [www.rfblatex.com](http://www.rfblatex.com)



## Authorized Distributor Letter

To Whom It May Concern:

We are pleased to announce that Super 7 Wholesale Limited located at 18 Wildmere Road, Wildmere Industrial Estate, Banbury, Oxfordshire, OX16 3JU, United Kingdom is an authorized distributor for RFB Latex Ltd.

Here to executed by,

K.S Ratra  
Director  
RFB Latex Limited



## Establishment Registration &amp; Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)[New Search](#)[Back To Search Results](#)

**Establishment:**  
RFB Gloves  
SDF No. C-08(C)  
Noida Special Economic Zone  
NOIDA Uttar Pradesh, IN 201305  
**Registration Number:** 3008266585  
**FEI Number\*:** 3008266585  
**Status:** Active  
**Date Of Registration Status:** 2020

**Owner/Operator:**  
RFB Gloves  
SDF No. C-80 (C), Noida Special Economic  
Noida, Uttar Pradesh IN 201305  
**Owner/Operator Number:** [8041135](#)

**Official Correspondent:**  
David Lennarz  
Registrar Corp  
144 Research Drive  
Hampton, VA 23666  
**Phone:** 1-757-2240177

**US Agent:**  
David Lennarz  
Registrar Corp  
144 Research Drive  
Hampton, VA US 23666  
**Phone:** 757 2240177 Ext  
**Fax:** 757 2240179  
**Email:** [David.Lennarz@Registrarcorp.Com](mailto:David.Lennarz@Registrarcorp.Com)

\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 08/17/2020

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## U.S. Food and Drug Administration

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)  
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U.S. Department of Health &amp; Human Services



EUROPEAN INSPECTION AND CERTIFICATION COMPANY S.A.

CERTIFICATE No: EUIS-2327-3/20

## CERTIFICATE OF COMPLIANCE

This to Certify that the  
Quality Management System  
Of

**RFB LATEX LTD.**

Plot 24, 78-80, Noida Special Economic Zone, Phase II  
Gautam Budha Nagar, U.P-201305, INDIA

**Has been assessed and conforms to:**

**ISO 9001:2015**

Applicable to following Scope:

**Design, Manufacture, Import/Export & Supply of  
POWDERED AND POWDER FREE SURGICAL, EXAMINATION, GYNAECOLOGICAL AND ORTHOPAEDIC GLOVES AND  
INDUSTRIAL, HOUSEHOLD, AND OTHER PPE GLOVES**

Certificate Issue Date: 11/03/2020  
Certificate Expiry Date: 10/03/2023

Third Party Authority Stamp



For EUROCERT S.A.

DIRECTOR OF CERTIFICATION



# Compliance Certificate

This is to Certify that the  
Good Manufacturing Practice  
of

## RFB LATEX LIMITED

Plot 24, 78-80, Noida Special Economic Zone, Phase II,  
Gautam Budha Nagar, U.P-201305, INDIA

Has been assessed and conforms to:

### WHO-GMP

Applicable to Following Scope:

Design, Manufacture, Import/Export & Supply of Powdered and Powder  
Free Surgical, Examination, Gynecological and Orthopedic Gloves &  
Industrial, Household and Other PPE Gloves.

"Validity of This Certificate is Subject to Annual Surveillance Audits Done Successfully"

Certificate Number: C2027138

Certificate Issue Date: 20/03/2020

Certificate Expiry Date: 19/03/2023

To Verify this certificate visit at website [www.dabaccreditation.org](http://www.dabaccreditation.org)



Certification Manager

### Deutsche Accreditation Board

Otto-Hang-Ring 6, D-81739 Muenchen, Germany

E-mail: [info@dabaccreditation.org](mailto:info@dabaccreditation.org), Website: [www.dabaccreditation.org](http://www.dabaccreditation.org)

The client is requested to check the certificate details at our website [www.dabaccreditation.org](http://www.dabaccreditation.org)  
under the heading of registration details by entering their certificate number and inform us in case  
of any discrepancy at our above email id.





# RFB LATEX LIMITED

PLOT No. 78-80, NOIDA SPECIAL ECONOMIC ZONE, NOIDA - 201305 INDIA

TEL : +91 120 4944150 FAX : +91 120 4944190, +91 11 66173971

E-mail : rfblatex@rfblatex.com Website : www.rfblatex.com

## EC DECLARATION OF CONFORMITY

We,

RFB Latex Limited, #78-80, Noida Special Economic Zone, Noida Phase-II, Distt. G.B. Nagar- UP-201305, India

*Declares that Examination Gloves has been classified as class Is(Annex IX Rule 5) is in conformity with the essential requirements and provisions of council directive 93/42/EEC amended by MDD/2007/47/EEC*

**PRODUCT NAME: EXAMINATION GLOVES:**

PRODUCT CATEGORY	GMDN code	CLASS	STERILE	Rule	Conformity route
LATEX EXAMINATION GLOVES	34020	Is	yes	5	Annex II of directive 93/42/EEC amended by MDD/2007/47/EEC
NITRILE EXAMINATION GLOVES					

*As per following harmonised standard numbers.*

*is subject to the procedure set out in Annex II of directive 93/42/EEC amended by MDD/2007/47/EEC.*

Signature :

Name : P S RATRA

Designation : Managing Director

Date & Seal : 25.05.2020

Seal :



**RFB LATEX LIMITED**

AN ISO 9001:2008, 13485:2003 CERTIFIED COMPANY

Regd. Office : K-185, Surya Plaza, Sarai Julena, New Friends Colony, New Delhi-110025

Corporate Identity No.: U74899DL1989PLC035091





# CERTIFICATE

*This is to Certify that the*  
*Medical Devices – Quality Management System*  
*of*  
**RFB LATEX LTD.**

**PLOT 24, 78-80, NOIDA SPECIAL ECONOMIC ZONE, PHASE II,  
GAUTAM BUDHA NAGAAR, UP, INDIA-201305**

**has been independently assessed and is compliant  
with the requirements of**

**ISO 13485:2016**

**This Certificate is applicable to the following products or service ranges:**

**DESIGN, MANUFACTURE IMPORT/EXPORT & SUPPLY OF POWDERED AND  
POWDER FREE SURGICAL, EXAMINATION, GYNAECOLOGICAL  
AND ORTHOPAEDIC, GLOVES AND X-RAY AND OTHER  
RADIATION RESISTANT GLOVES**

**:: Certificate No :: IN85597H**

<b>Date of initial registration</b>	<b>17 May 2019</b>
<b>Date of this Certificate</b>	<b>05 June 2020</b>
<b>Surveillance audit on or before</b>	<b>16 May 2021</b>
<b>Recertification Due / Certificate expiry</b>	<b>16 May 2022</b>

This Certificate is property of LMS Certifications and remains valid  
subject to satisfactory surveillance audits.

**Director**

For verification and updated information concerning the present certificate visit to [www.lmscert.com](http://www.lmscert.com)

This Certificate is the property of LMS Certification Limited and shall be returned immediately when demanded.



**LMS Certification Limited**  
35 Park Hill, Huddersfield, HD2 1QG, West Yorkshire, United Kingdom.  
Phone : +44 2089355094  
Visit :- [www.lmscert.com](http://www.lmscert.com)  
E-mail :- [info@lmscert.com](mailto:info@lmscert.com)



LMS/IAS/F109MDQ/17/REV02

**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****RFB LATEX LIMITED**

PLOT NO-78-80, NOIDA SPECIAL ECONOMIC ZONE  
UTTAR PRADESH, NOIDA-201305  
INDIA

**CONTACT PERSON : MR. HEERA RATRA****THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :**

**PRODUCT DESCRIPTION** NITRILE POWDER FREE GLOVES  
**COLOUR** BLUE  
**BUYER** RFB LATEX LIMITED  
**COUNTRY OF ORIGIN** INDIA  
**SAMPLE RECD ON** 28/04/2016  
**TEST PERFORMING DATE** 29/04/2016 TO 15/06/2016

**RESULT SUMMARY**

TESTS NAME	COMMENTS
<b>1. French Arrêté du 9 November 1994, French Décret 2007-766 with amendments and DGCCRF Information Notice 2004-64 with amendments.</b>	--
a) Rubber – Overall Migration	Pass
b) Rubber -Specific migration of Primary Aromatic Amine	Pass
c) Rubber – Peroxide Value	Pass
d) Rubber – Volatile Organic Matter	Pass
e) Specific Migration of Formaldehyde	Pass
<b>2. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 &amp; 31 with Amendments, European Commission Directive 93/11/EEC, and BfR Recommendation.</b>	--
a) Rubber – Lead, Cadmium and Zinc Content	Pass
b) Rubber – Specific Migration of Phthalates	Pass
<b>3. Rubber – Polycyclic Aromatic Hydrocarbons (PAHs) Content</b>	See Results
<b>4. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 &amp; 31 with Amendments</b>	--
a) Sensorial Examination Odour and Taste Test	Pass
b) Colour Release	Pass
<b>5. Bisphenol A (BPA) Content</b>	Pass

**Per Pro SGS India Pvt Ltd.****Subasini Saraswat****Asst. Manager**

Email your Test Report Related Enquiries at Feedback.HLT@sgs.com

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

JOE No. : 1648802143

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# TEST REPORT

REVISED

Report No. : MAN:HL:7480005029-1

DATE : 19<sup>th</sup> July, 2016



Revision remark: Report has been revised to change the test condition of Overall migration as per client's request.

## Test Results:

### 1. French Arrêté du 9 November 1994, French Décret 2007-766 with amendments and DGCCRF Information Notice 2004-64 with amendments:

#### a) Rubber – Overall migration

Method : With reference to EN1186

Simulant Used	Test Condition	Result(mg/dm <sup>2</sup> )	Permissible Limit(mg/dm <sup>2</sup> )
10% Ethanol (V/V) Aqueous Solution	2 Hours at 40 °C	3.625	10
3% Acetic Acid (W/V) Aqueous Solution	2 Hours at 40 °C	9.156	10
Isooctane	2 Hours at 40 °C	ND	10
Comment	--	PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

- Note:
1. mg/dm<sup>2</sup> = milligram per square decimeter
  2. °C = degree Celsius
  3. ND = Not Detected
  4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.
  5. Reporting Limit : 2.0 (mg/dm<sup>2</sup>)
  6. Isooctane is a substitute of olive oil.

#### b) Rubber – Specific migration of Primary Aromatic Amine

Method: With reference to EN 13130-1:2004 and BfR Recommendation XXI. Analysis was performed by UV-vis Spectrophotometer.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 70 °C for 02 hours

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Specific migration of Primary Aromatic Amine	ND	0.01	1
Comment	PASS	--	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

- Note :
1. mg/kg = milligram per kilogram of foodstuff in contact with
  2. °C = degree Celsius
  3. ND = Not Detected
  4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****c) Rubber – Peroxide value**

Method: With reference to European Pharmacopoeia, 2005.

Test Item	Result	Requirement
Peroxide Value	Absent	Absent
Comment	PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note: 1. Requirement is according to French Arrêté du 9 Novembre 1994.

**d) Rubber – Volatile organic matter**

Method: With reference to French Arrêté du 25 Novembre 1992 Annex III.

Test Item	Result (% w/w)	Reporting Limit (% w/w)	Permissible Limit (% w/w)
Volatile Organic Matter (VOM)	0.19	0.1	0.5
Comment	PASS	--	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note : 1. % w/w = percentage of weight by weight  
2. ND = Not Detected  
3. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

**e) Rubber – Specific migration of Formaldehyde**

Method: With reference to EN 13130-1:2004. Analysis was performed by UV-vis Spectrophotometer.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 70°C for 2 hours

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Specific migration of Formaldehyde	ND	0.1	3
Comment	PASS	--	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note: 1. Mg/kg = milligram per kilogram of foodstuff in contact with  
2. ND = Not Detected  
3. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016**

2. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments, European Commission Directive 93/11/EEC, and BfR Recommendation.

**a) Rubber – Lead, Cadmium and Zinc Content:**

Method: Lead, Cadmium and Zinc content : Acid digestion. Analysis was performed by AAS / ICP-OES.

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Lead Content	12.59	2	30
Zinc Content	1781.25	100	30000
Cadmium Content	ND	2	Absent
Comment	PASS	--	--

**Sample Description :** NITRILE POWDER FREE GLOVES.

- Note:**
1. Lead, Zinc and Cadmium content: mg/kg = milligram per kilogram
  2. ND = Not Detected
  3. Permissible Limit is according to German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****b) Rubber – Specific Migration of Phthalates:**

Method: With reference to EN 13130-1:2004. Analysis was performed by GC-MS.

Simulant Used: 95% Ethanol

Test Condition: 70°C for 02 hours

Test Item	3rd Migration Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Dibutyl phthalate (DBP)	ND	0.06	0.3
Benzylbutyl phthalate (BBP)	ND	0.06	30
Bis-(2-ethylhexyl) phthalate (DEHP)	ND	0.06	1.5
Diisononyl phthalate + Diisodecyl phthalate (DINP + DIDP)	ND	0.25	9
Diallyl phthalate (DAP)	ND	0.25	0.01
Comment	PASS	--	--

Simulant Used: Isooctane

Test Condition: 70°C for 02 hours

Test Item	3rd Migration Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Dibutyl phthalate (DBP)	ND	0.06	0.3
Benzylbutyl phthalate (BBP)	ND	0.06	30
Bis-(2-ethylhexyl) phthalate (DEHP)	ND	0.06	1.5
Diisononyl phthalate + Diisodecyl phthalate (DINP + DIDP)	ND	0.25	9
Diallyl phthalate (DAP)	ND	0.25	0.01
Comment	PASS	--	--

**Sample Description : NITRILE POWDER FREE GLOVES**

- Note:
1. mg/kg = milligram per kilogram of foodstuff in contact with
  2. °C = degree Celsius
  3. ND = Not Detected
  4. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****3. Rubber – Polycyclic Aromatic Hydrocarbons (PAHs) Content**

Method: With reference to ZEK 01.4-08 with column clean-up. Analysis was performed by GC-MS.

Test Item	CAS number	Result
		(mg/kg)
		1
Naphthalene	91-20-3	ND
Acenaphthylene	208-96-8	ND
Acenaphthene	83-32-9	ND
Fluorene	86-73-7	ND
Phenanthrene	85-01-8	ND
Anthracene	120-12-7	ND
Fluoranthene	206-44-0	ND
Pyrene	129-00-0	ND
Benz[a]anthracene	56-55-3	ND
Chrysene	218-01-9	ND
Benzo[b]fluoranthene and Benzo[j]fluoranthene	205-99-2 205-82-3	ND
Benzo[k]fluoranthene	207-08-9	ND
Benzo[a]pyrene	50-32-8	ND
Benzo[e]pyrene	192-97-2	ND
Indeno[1,2,3-cd]pyrene	193-39-5	ND
Dibenz[a,h]anthracene	53-70-3	ND
Benzo[g,h,i]perylene	191-24-2	ND
Total 18 PAHs	--	ND
Conclusion		See Requirement (ZEK 01.4-08)

**Sample Description :** NITRILE POWDER FREE GLOVES.

- Note :**
1. DL: 0.2 mg/kg
  2. ND: Not Detected
  3. Testing has been subcontracted to SGS approved lab

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****ZEK 01.4-08: Restraining maximum values for products :**

Parameter	Category 1	Category 2	Category 3
	Material indented to be put in the mouth or material for toys with normal skin contact for children aged < 36 months	Materials those are not included in Category 1, with predictable contact with the skin longer than 30 s. (long-term skin contact).	Materials those are not included in Category 1 or 2, with predictable skin contact up to 30 s (short-term skin contact).
Benzo[a]pyrene (mg/kg)	< 0.2***	1	20
Sum of 18 PAH (mg/kg)**	< 0.2***	10	200

**Note:**

&lt; = less than

mg/kg = milligram per kilogram

ND = Not Detected

The detection limit of each of the individual compound is 0.2 mg/kg.

\* = exceeds the limit

\*\* Only PAH substances &gt;0.2 mg/kg are taken into account while calculating the sum of PAHs

\*\*\* In case that the maximum values exceed the limits of category 1, but are within the limits of category 2, one may confirm the suitability of the tested material which is indented to be put in the mouth by additional specific migration tests of PAH components based on DIN EN 1186ff/EN 13130 and §64 LFGB 80.30-1. The conclusion of the migration test results must be made based on food law criteria.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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# TEST REPORT

REVISED

Report No. : MAN:HL:7480005029-1

DATE : 19<sup>th</sup> July, 2016



## 4. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments

### a) Sensory Examination – Odour and Taste Test

Method: With reference to DIN10955: 2004  
Test condition: 40°C for 10 days  
Test media: Distilled Water  
No. of panelist: 6

Test Results :

Test Media	Test Item	Result	Maximum Permissible Limit
		1	
Distilled water	Sensorial examination odour	0	2.5
	Sensorial examination taste	0	2.5
Comment		PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note: 1. Intensity scale (rounded at 0.5):

- 0 – no perceptible difference
- 1 – just perceptible difference
- 2 – slight difference
- 3 – marked difference
- 4 – strong difference

- 2. Permissible Limit is according to German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments.
- 3. Testing has been performed as per client's request.
- 4. Testing has been subcontracted to SGS approved lab.

### b) Colour Release :

Method: With reference to Kunststoffe im Lebensmittelverkehr, Part B II IX.

Simulant Used	Test condition	Result	Requirement
3% Acetic Acid (W/V) Aqueous Solution	5 hours at 50 °C	No color release observed	No colour release
Comment	--	PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note : Permissible Limit is according to BfR Recommendation IX.

This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India

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# TEST REPORT

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Report No. : MAN:HL:7480005029-1

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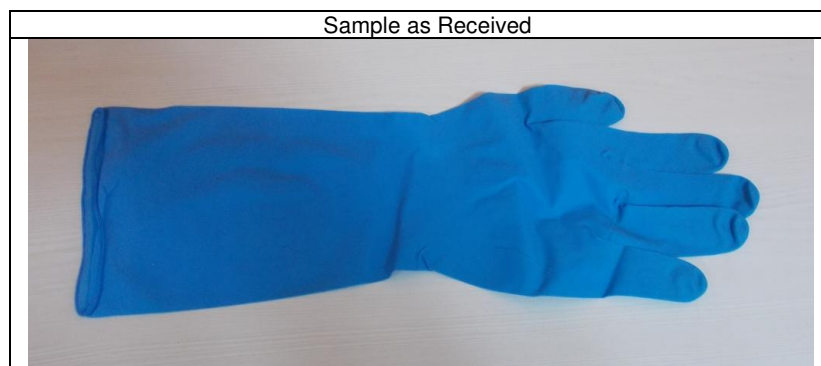


## 5. BISPHENOL A (BPA) CONTENT:

TEST NAME/METHOD	RESULT (mg/kg)	REQUIREMENT (mg/kg)
<b>BISPHENOL A (BPA) CONTENT</b> (Solvent extraction and analysis by LC/MS)	NITRILE POWDER FREE GLOVES : ND	1.0

### Note:

1. Detection Limit = 1 mg/kg, ND=Not Detected
2. mg/kg = milligram per kilograms
3. Requirement has been taken with ref. to. EU10/2011.
4. Testing has been performed as per applicant's request.
5. Testing has been subcontracted to SGS approved lab.



\*\*\*\*\*End of Report\*\*\*\*\*

This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****RFB LATEX LIMITED**

PLOT NO-78-80, NOIDA SPECIAL ECONOMIC ZONE  
UTTAR PRADESH, NOIDA-201305  
INDIA

**CONTACT PERSON : MR. HEERA RATRA****THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :**

**PRODUCT DESCRIPTION** NITRILE POWDER FREE GLOVES  
**COLOUR** BLUE  
**BUYER** RFB LATEX LIMITED  
**COUNTRY OF ORIGIN** INDIA  
**SAMPLE RECD ON** 28/04/2016  
**TEST PERFORMING DATE** 29/04/2016 TO 15/06/2016

**RESULT SUMMARY**

TESTS NAME	COMMENTS
<b>1. French Arrêté du 9 November 1994, French Décret 2007-766 with amendments and DGCCRF Information Notice 2004-64 with amendments.</b>	--
a) Rubber – Overall Migration	Pass
b) Rubber -Specific migration of Primary Aromatic Amine	Pass
c) Rubber – Peroxide Value	Pass
d) Rubber – Volatile Organic Matter	Pass
e) Specific Migration of Formaldehyde	Pass
<b>2. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 &amp; 31 with Amendments, European Commission Directive 93/11/EEC, and BfR Recommendation.</b>	--
a) Rubber – Lead, Cadmium and Zinc Content	Pass
b) Rubber – Specific Migration of Phthalates	Pass
<b>3. Rubber – Polycyclic Aromatic Hydrocarbons (PAHs) Content</b>	See Results
<b>4. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 &amp; 31 with Amendments</b>	--
a) Sensorial Examination Odour and Taste Test	Pass
b) Colour Release	Pass
<b>5. Bisphenol A (BPA) Content</b>	Pass

**Per Pro SGS India Pvt Ltd.****Subasini Saraswat****Asst. Manager**

Email your Test Report Related Enquiries at Feedback.HLT@sgs.com

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****Revision remark:** Report has been revised to change the test condition of Overall migration as per client's request.**Test Results:****1. French Arrêté du 9 November 1994, French Décret 2007-766 with amendments and DGCCRF Information Notice 2004-64 with amendments:****a) Rubber – Overall migration**

Method : With reference to EN1186

Simulant Used	Test Condition	Result(mg/dm <sup>2</sup> )	Permissible Limit(mg/dm <sup>2</sup> )
10% Ethanol (V/V) Aqueous Solution	2 Hours at 40 °C	3.625	10
3% Acetic Acid (W/V) Aqueous Solution	2 Hours at 40 °C	9.156	10
Isooctane	2 Hours at 40 °C	ND	10
Comment	--	PASS	--

**Sample Description :** NITRILE POWDER FREE GLOVES.

- Note:
1. mg/dm<sup>2</sup> = milligram per square decimeter
  2. °C = degree Celsius
  3. ND = Not Detected
  4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.
  5. Reporting Limit : 2.0 (mg/dm<sup>2</sup>)
  6. Isooctane is a substitute of olive oil.

**b) Rubber – Specific migration of Primary Aromatic Amine**

Method: With reference to EN 13130-1:2004 and BfR Recommendation XXI. Analysis was performed by UV-vis Spectrophotometer.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 70 °C for 02 hours

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Specific migration of Primary Aromatic Amine	ND	0.01	1
Comment	PASS	--	--

**Sample Description :** NITRILE POWDER FREE GLOVES.

- Note :
1. mg/kg = milligram per kilogram of foodstuff in contact with
  2. °C = degree Celsius
  3. ND = Not Detected
  4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****c) Rubber – Peroxide value**

Method: With reference to European Pharmacopoeia, 2005.

Test Item	Result	Requirement
Peroxide Value	Absent	Absent
Comment	PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note: 1. Requirement is according to French Arrêté du 9 Novembre 1994.

**d) Rubber – Volatile organic matter**

Method: With reference to French Arrêté du 25 Novembre 1992 Annex III.

Test Item	Result (% w/w)	Reporting Limit (% w/w)	Permissible Limit (% w/w)
Volatile Organic Matter (VOM)	0.19	0.1	0.5
Comment	PASS	--	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note : 1. % w/w = percentage of weight by weight  
2. ND = Not Detected  
3. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

**e) Rubber – Specific migration of Formaldehyde**

Method: With reference to EN 13130-1:2004. Analysis was performed by UV-vis Spectrophotometer.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 70°C for 2 hours

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Specific migration of Formaldehyde	ND	0.1	3
Comment	PASS	--	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note: 1. Mg/kg = milligram per kilogram of foodstuff in contact with  
2. ND = Not Detected  
3. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016**

2. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments, European Commission Directive 93/11/EEC, and BfR Recommendation.

**a) Rubber – Lead, Cadmium and Zinc Content:**

Method: Lead, Cadmium and Zinc content : Acid digestion. Analysis was performed by AAS / ICP-OES.

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Lead Content	12.59	2	30
Zinc Content	1781.25	100	30000
Cadmium Content	ND	2	Absent
Comment	PASS	--	--

**Sample Description :** NITRILE POWDER FREE GLOVES.

- Note:**
1. Lead, Zinc and Cadmium content: mg/kg = milligram per kilogram
  2. ND = Not Detected
  3. Permissible Limit is according to German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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Report No. : MAN:HL:7480005029-1

DATE : 19<sup>th</sup> July, 2016



## b) Rubber – Specific Migration of Phthalates:

Method: With reference to EN 13130-1:2004. Analysis was performed by GC-MS.

Simulant Used: 95% Ethanol

Test Condition: 70°C for 02 hours

Test Item	3rd Migration Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Dibutyl phthalate (DBP)	ND	0.06	0.3
Benzylbutyl phthalate (BBP)	ND	0.06	30
Bis-(2-ethylhexyl) phthalate (DEHP)	ND	0.06	1.5
Diisononyl phthalate + Diisodecyl phthalate (DINP + DIDP)	ND	0.25	9
Diallyl phthalate (DAP)	ND	0.25	0.01
Comment	PASS	--	--

Simulant Used: Isooctane

Test Condition: 70°C for 02 hours

Test Item	3rd Migration Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
Dibutyl phthalate (DBP)	ND	0.06	0.3
Benzylbutyl phthalate (BBP)	ND	0.06	30
Bis-(2-ethylhexyl) phthalate (DEHP)	ND	0.06	1.5
Diisononyl phthalate + Diisodecyl phthalate (DINP + DIDP)	ND	0.25	9
Diallyl phthalate (DAP)	ND	0.25	0.01
Comment	PASS	--	--

## Sample Description : NITRILE POWDER FREE GLOVES

- Note:
1. mg/kg = milligram per kilogram of foodstuff in contact with
  2. °C = degree Celsius
  3. ND = Not Detected
  4. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments.

This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India

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## TEST REPORT

REVISED

Report No. : MAN:HL:7480005029-1

DATE : 19<sup>th</sup> July, 2016



### 3. Rubber – Polycyclic Aromatic Hydrocarbons (PAHs) Content

Method: With reference to ZEK 01.4-08 with column clean-up. Analysis was performed by GC-MS.

Test Item	CAS number	Result
		(mg/kg)
		1
Naphthalene	91-20-3	ND
Acenaphthylene	208-96-8	ND
Acenaphthene	83-32-9	ND
Fluorene	86-73-7	ND
Phenanthrene	85-01-8	ND
Anthracene	120-12-7	ND
Fluoranthene	206-44-0	ND
Pyrene	129-00-0	ND
Benz[a]anthracene	56-55-3	ND
Chrysene	218-01-9	ND
Benzo[b]fluoranthene and Benzo[j]fluoranthene	205-99-2 205-82-3	ND
Benzo[k]fluoranthene	207-08-9	ND
Benzo[a]pyrene	50-32-8	ND
Benzo[e]pyrene	192-97-2	ND
Indeno[1,2,3-cd]pyrene	193-39-5	ND
Dibenz[a,h]anthracene	53-70-3	ND
Benzo[g,h,i]perylene	191-24-2	ND
Total 18 PAHs	--	ND
Conclusion		See Requirement (ZEK 01.4-08)

**Sample Description :** NITRILE POWDER FREE GLOVES.

**Note :** 1. DL: 0.2 mg/kg  
2. ND: Not Detected  
3. Testing has been subcontracted to SGS approved lab

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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**TEST REPORT**

REVISED

**Report No. : MAN:HL:7480005029-1****DATE : 19<sup>th</sup> July, 2016****ZEK 01.4-08: Restraining maximum values for products :**

Parameter	Category 1	Category 2	Category 3
	Material indented to be put in the mouth or material for toys with normal skin contact for children aged < 36 months	Materials those are not included in Category 1, with predictable contact with the skin longer than 30 s. (long-term skin contact).	Materials those are not included in Category 1 or 2, with predictable skin contact up to 30 s (short-term skin contact).
Benzo[a]pyrene (mg/kg)	< 0.2***	1	20
Sum of 18 PAH (mg/kg)**	< 0.2***	10	200

**Note:**

&lt; = less than

mg/kg = milligram per kilogram

ND = Not Detected

The detection limit of each of the individual compound is 0.2 mg/kg.

\* = exceeds the limit

\*\* Only PAH substances &gt;0.2 mg/kg are taken into account while calculating the sum of PAHs

\*\*\* In case that the maximum values exceed the limits of category 1, but are within the limits of category 2, one may confirm the suitability of the tested material which is indented to be put in the mouth by additional specific migration tests of PAH components based on DIN EN 1186ff/EN 13130 and §64 LFGB 80.30-1. The conclusion of the migration test results must be made based on food law criteria.

**This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India**

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Report No. : MAN:HL:7480005029-1

DATE : 19<sup>th</sup> July, 2016



## 4. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments

### a) Sensory Examination – Odour and Taste Test

Method: With reference to DIN10955: 2004  
Test condition: 40°C for 10 days  
Test media: Distilled Water  
No. of panelist: 6

Test Results :

Test Media	Test Item	Result	Maximum Permissible Limit
		1	
Distilled water	Sensorial examination odour	0	2.5
	Sensorial examination taste	0	2.5
Comment		PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note: 1. Intensity scale (rounded at 0.5):

- 0 – no perceptible difference
- 1 – just perceptible difference
- 2 – slight difference
- 3 – marked difference
- 4 – strong difference

- 2. Permissible Limit is according to German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments.
- 3. Testing has been performed as per client's request.
- 4. Testing has been subcontracted to SGS approved lab.

### b) Colour Release :

Method: With reference to Kunststoffe im Lebensmittelverkehr, Part B II IX.

Simulant Used	Test condition	Result	Requirement
3% Acetic Acid (W/V) Aqueous Solution	5 hours at 50 °C	No color release observed	No colour release
Comment	--	PASS	--

**Sample Description** : NITRILE POWDER FREE GLOVES.

Note : Permissible Limit is according to BfR Recommendation IX.

This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India

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# TEST REPORT

REVISED

Report No. : MAN:HL:7480005029-1

DATE : 19<sup>th</sup> July, 2016

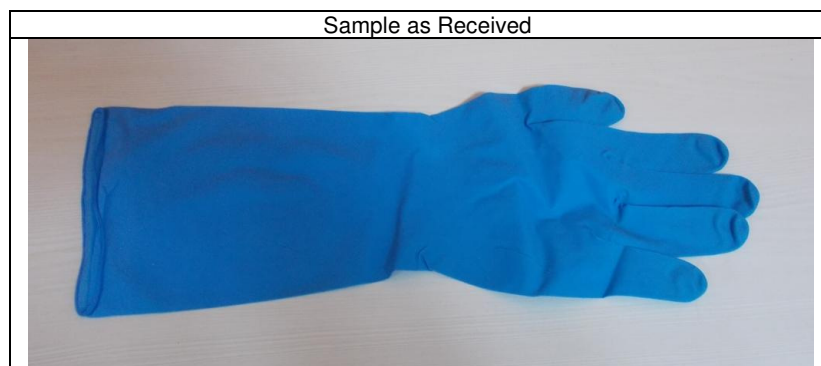


## 5. BISPHENOL A (BPA) CONTENT:

TEST NAME/METHOD	RESULT (mg/kg)	REQUIREMENT (mg/kg)
<b>BISPHENOL A (BPA) CONTENT</b> (Solvent extraction and analysis by LC/MS)	NITRILE POWDER FREE GLOVES : ND	1.0

### Note:

1. Detection Limit = 1 mg/kg, ND=Not Detected
2. mg/kg = milligram per kilograms
3. Requirement has been taken with ref. to. EU10/2011.
4. Testing has been performed as per applicant's request.
5. Testing has been subcontracted to SGS approved lab.



\*\*\*\*\*End of Report\*\*\*\*\*

This Report cancels and supersedes the Report No 7480005029 Dated 23/05/2016 issued by SGS India

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